



September 15, 2021

Possis Medical, Inc.  
Frank Freedman  
Senior Regulatory Affairs Associate  
9055 Evergreen Blvd., NW  
Minneapolis, Minnesota 55433-8003

Re: K071514

Trade/Device Name: AngioJet XPEEDIOR Rheolytic Thrombectomy Catheter  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy catheter  
Regulatory Class: Class II  
Product Code: QEZ, KRA

Dear Frank Freedman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 31, 2007. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, [Gregory.Oconnell@FDA.HHS.gov](mailto:Gregory.Oconnell@FDA.HHS.gov).

Sincerely,

Gregory W. O'Connell -S

Digitally signed by  
Gregory W. O'Connell -S  
Date: 2021.09.15  
10:18:17 -04'00'

Gregory O'Connell  
Assistant Director  
DHT2C: Division of Coronary  
and Peripheral Intervention Devices  
OHT2: Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 31 2007

Possis Medical, Inc.  
c/o Dr. Frank Freedman  
Senior Regulatory Affairs Associate  
9055 Evergreen Blvd. NW  
Minneapolis, MN 55433

Re: K071514  
Trade/Device Name: AngioJet XPEEDIOR Rheolytic Thrombectomy Catheter  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy Catheter  
Regulatory Class: Class II  
Product Code: DXE, KRA  
Dated: June 1, 2007  
Received: June 4, 2007

Dear Dr. Freedman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

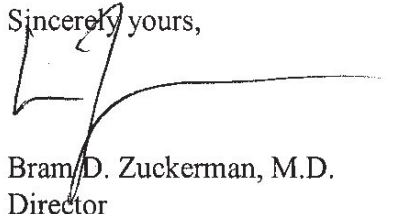
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K071514

Device Name: Traditional 510(k) Notification  
AngioJet® XPEEDIOR® Rheolytic Thrombectomy Catheter

**Indications For Use:** The AngioJet XPEEDIOR Rheolytic Thrombectomy Catheter is intended for use with the AngioJet System in breaking apart and removing thrombus from:

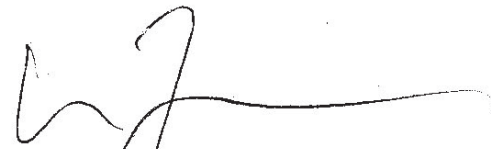
- upper and lower extremity peripheral arteries  $\geq 3.0$  mm in diameter and
- upper extremity and infrainguinal lower extremity peripheral veins  $\geq 3.0$  mm in diameter.

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
NEEDED)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K071514

## 5. 510(k) Summary

**Submitter:** Frank B. Freedman, Ph.D.  
Possis Medical, Inc.  
9055 Evergreen Boulevard, N.W.  
Coon Rapids, MN 55433  
Phone: 763.780.4555  
Fax: 763.780.2227

JUL 31 2007

<b>Contact Person:</b>	<u>Primary Contact</u>	<u>Secondary Contact</u>
	Frank B. Freedman	Mark D. Stenoien
	Possis Medical, Inc.	Possis Medical, Inc.

**Device Common Name:** Thrombectomy Catheter

**Device Trade Name:** AngioJet® XPEEDIOR® Rheolytic Thrombectomy Catheter

**Device Classification Name:** Embolectomy Catheter

**Predicate Devices:** AngioJet XPEEDIOR Rheolytic Thrombectomy Catheter (K040013, K052256 and K061951)

### Device Description

When used with the AngioJet System, the XPEEDIOR Rheolytic Thrombectomy Catheter uses high velocity saline jets to percutaneously break-up and remove thrombus. These saline jets are contained within the Catheter and provide the suction that produces this effect.

### Indications for Use

The currently cleared indications for use were expanded to include breaking apart and removing thrombus from:

- upper and lower peripheral extremity arteries  $\geq 3.0$  mm in diameter and
- upper extremity and infrainguinal lower extremity peripheral veins  $\geq 3.0$  mm in diameter.

### Comparison to Predicate Devices

No design, packaging, sterilization or other device change was required to expand the AngioJet XPEEDIOR Rheolytic Thrombectomy Catheter indications for use (K040013, K052556 and K061951).

### Supporting Information

Applicable preclinical and clinical experience supports the expanded indications for use.